

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jiang, et al.	Art Unit:	1775
Serial No.:	10/711,154	Examiner:	Timothy M Speer
Filed:	08/27/2004		
Docket No.:	A382-USA		
For:	Material and Method to Prevent Low Temperature Degradation of Zirconia in Biomedical Implants		

VIA EFS-WEB

**Mail Stop Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450**

APPEAL BRIEF (37 C.F.R. § 41.37)

This brief is in furtherance of the Notice of Appeal, filed in this case on June 08, 2006.

The fees required under § 41.20, and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF or EFS-Web filing documentation.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is: The Alfred E. Mann Foundation, a California Corporation, by virtue of an assignment from the inventor, recorded 08/27/2004 at Reel 015049, Frame 0853.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal:

there are no such appeals or interferences.

III. STATUS OF CLAIMS

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: 7

B. STATUS OF ALL THE CLAIMS

1. Claims cancelled:

6 to 12

2. Claims withdrawn from consideration but not cancelled:

none

3. Claims objected to:

none

4. Claims allowed or confirmed:

none

5. Claims rejected:

1 to 5; 13 to 14

C. CLAIMS ON APPEAL

The claims on appeal are:

1 to 5; 13 to 14

IV. STATUS OF AMENDMENTS

An amendment was filed by appellants on December 6, 2005. On May 9, 2006 a final Office action was mailed to Applicant. A pre-appeal brief was filed on June 8, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is an independent claim and claims 2-5 are dependent on claim 1. Claim 13 is an independent claim and claim 14 is dependent on claim 13.

The claims are directed to an yttria-stabilized tetragonal zirconia polycrystal

substrate material having a total porosity of less than about 1.0%. Claim 1 limits the matter to a coating of alumina deposited by ion beam assisted deposition [IBAD] while claim 13 limits the matter to a moisture resistant coating of alumina deposited on the substrate.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4 and 13-14 stand rejected under 35 USC 103(a) as being unpatentable over Schubert (Surface Stabilization of Y-TZP, British Ceramic Proceedings, 34, pp 157-160, 1984) in view of Hida (US 5,192,720).

Claim 5 stands rejected under 35 USC 103(a) as being unpatentable over Schubert in view of Hida (US 5,192,720) and further in view of Toibana (US 4,507,224).

VII. ARGUMENT

A. Claims 1-4 and 13-14 stand rejected under 35 USC 103(a) as being unpatentable over Schubert (Surface Stabilization of Y-TZP, British Ceramic Proceedings, 34, pp 157-160, 1984) in view of Hida (US 5,192,720).

Product-by-Process Claim 1 Process Limitation

The Examiner's objections raised in the Office action mailed on 5/9/2006 are identical in wording and content, generally, to those raised in the Office action mailed on 11/18/2005, hence all references herein are to the later mailed final Office action.

The Examiner states at page 2 of the Office Action mailed on 5/9/2006, "Regarding the recitation of the process limitation 'ion beam assisted deposition,' this limitation is being given no patentable weight, since an invention recited in a product-by-process claim is a product and not a process. The method by which a claimed product may be made is not germane to patentability of the claimed product unless applicant demonstrates that the recited process step produces a materially different product. In the present case, no such evidence has been

adduced.” Applicant disagrees with the rejection and argues that the phrase is a limitation as follows:

1. Applicant has demonstrated that the recited process step produces a materially different product. The ion beam assisted deposition process (IBAD) discussed in the Application [para 17] is described as creating a conformal coating versus alternative routes that result in a significantly different coating. It is disclosed that the resulting alumina coating is dense and strongly adherent to the Y-TZP substrate. The products of the IBAD formed coating are discussed further [para 20] when it is disclosed that the preferred alpha-alumina composition phase is thus formed. It is further disclosed [para 21] that the IBAD alumina coating offers excellent resistance to moisture penetration and diffusion (i.e., it is hermetic). That is, Applicant has demonstrated that the IBAD process produced a materially different product that that created by other process that are known to persons skilled in the art.

2. The Examiner offered no authority in support of the conclusion that the limitation to IBAD coating should be given no patentable weight. The claim is in an allowable form [MPEP 2173.05p] and, as argued herein, IBAD is a limitation to an improved coating. Applicant asserts that it is clear that the claim is directed to the product and not the process, and is therefore allowable.

3. The Examiner rejects [Office action mailed 5/9/06, page 4, para no. 9] Applicant’s argument as restated here, that It is known and relied on that the Federal Circuit ruled that “process terms in product-by-process claims served as limitations in determining infringement.” *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 835, 846-47 (Fed. Cir. 1992). In the claim, “The molded innersole produced by the method of claim 1[.]” the court held that the same innersole would not infringe unless the method of claim 1 were used in its manufacture. The Examiner states at page 4, para 9 that Applicant’s reliance on *Atlantic Thermoplastic* is misplaced and not persuasive because the *Atlantic Thermoplastic* court was addressing product-by-process claims in the context of infringement and NOT ex parte prosecution. The Examiner offers no support for this distinction between infringement and ex parte analysis, nor does the *Atlantic*

Thermoplastics court so distinguish. Applicant argues that this distinction does not exist.

Therefore, Applicant argues that the limitation to IBAD should be given patentable weight in considering the allowability of claim 1. Applicant argues that the limitation to IBAD distinguishes the claim over the prior art and is therefore allowable.

The Rejection of Claims 1-4, 13-14 on Schubert and Hida is Overcome

Schubert is distinguishable from Applicant's invention. Applicant teaches coating of a dissimilar material, namely alumina, to a formed and densified yttria-stabilized tetragonal zirconia polycrystal substrate. Schubert, on the other hand, teaches converting the surface of the yttria-containing tetragonal ZrO₂ polycrystals [i.e., Y-TZP] during densification by sintering in a powder bed of stabilizing oxides, such as yttria, ceria, calcia and magnesia. Schubert places a green (i.e., unfired) Y-TZP compact in a powder bed and heats it, thereby allowing an oxide to diffuse into the original surface, thereby converting the original surface of the Y-TZP compact into a stabilized phase as a function of the amount of diffusion. The resulting converted body has a converted surface that is a gradient concentration of the stabilizing oxide from the surface to the center of the body. There is no definable coating on the surface of the treated body. It is known to those skilled in the art that diffusion is done *in situ* by converting the surface and the entire body of the compact in accord with the bulk diffusion rules of the stabilizing oxide as driven by the compositional gradient across the body itself. Diffusion and conversion of the ceramic phases does not involve application of a coating and nor does it employ a coating process. Schubert does not teach a coating, nor does Schubert mention the word "coating", except in an unrelated connection with an MgO transformation into a PSZ-type coating on annealing in air. Schubert does teach phase conversion via diffusion of the stabilizing oxide.

One cannot remove a "coating" from the body taught by Schubert because the compositional gradient is a continuum with no definite beginning and no

definite end, there is only a surface, a center, and another surface with a compositional gradient that is defined by the distance from the surface.

Schubert does not teach alumina at all. It is important to note that alumina is not a stabilizing oxide according to Schubert. The process taught by Schubert is inapplicable to deposition or utilization of alumina to form a coating. Alumina does not convert the surface of Y-TZP to a stabile phase, even if the process taught by Schubert is employed. Ultimately, there is no product that Schubert teaches having either an alumina coating or stabile surface phase that contains alumina.

The properties of the surface phase taught by Schubert are not relevant since the materials disclosed by Schubert and those claimed by Applicant are distinguishable. Applicant does not teach a stabile phase of zirconia, but teaches a coating of alumina on a stabile or partially stabile phase of zirconia.

Hida teaches a SIALON composition. The invention taught by Applicant is distinguishable over Hida. Hida teaches a composite material containing alumina, silicon, and a beta-sialon of the formula $\text{Si}_{6-z}\text{Al}_z\text{O}_z\text{N}_{8-z}$, where z is from 2.5 to 3.5. There is no zirconia or zirconium in the material taught by Hida.

Hida does not teach the formation of a stabile zirconia as taught by Applicant. In the section entitled, "Use of the beta-SIALON Material as a Sintering Aid", Hida teaches the use of the SIALON as an additive to aid in sintering of various ceramics, such as cordierite, mullite, and alumina, for example. Specifically at col 27, lines 1-4, Hida teaches the use of the SIALON as an additive to aid in sintering of zirconia. At col 27, lines 5-8 Hida teaches that the SIALON sintering aid produces a sintered zirconia body with improved properties. The suggestion by Hida at col 27, lines 1-4 that, "...the ceramic material to be sintered is zirconia which, preferably, has been partially stabilized with stabilizers such as alumina, magnesia, calcia, yttria, ceria, and the like" is unclear, cannot be interpreted by Applicant, and is nonsense. Hida proposes using SIALON as a sintering aid to form a stabile zirconia. Hida teaches that the zirconia has been partially stabilized with alumina, magnesia, calcia, yttria, ceria, and the like. How the zirconia became stabilized before sintering is not taught and defies normal materials processing.

Further, alumina is not a stabilizer for zirconia, while magnesia, calcia, yttria, and ceria are. What is meant by the phrase "and the like" is unknown. There are a limited number of material additives that combine to form stabile phases of zirconia and they do not include alumina. How Hida formed an alumina stabile phase of zirconia to be sintered and then sintered with SIALON as a sintering is not taught and defies good science.

Applicant finds no clarification or teaching in Hida to lend credibility or credence to the use of alumina as a phase stabilizer in zirconia.

Even if Hida does possess an alumina stabilized zirconia, this is distinguishable from the teaching of Applicant, which teaches an alumina coating on yttria stabilized zirconia. The zirconia taught by Applicant is not stabilized with alumina and contains no alumina.

During patent examination, the U.S. Patent Office bears the initial burden of presenting a *prima facie* case of unpatentability. See *In Re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992). When the U.S. Patent Office fails to meet this burden, the appellant is entitled to the patent. However, when a *prima facie* case is made, the burden shifts to the appellant to come forward with evidence and/or arguments supporting patentability. Patentability *vel non* is then determined on the entirety of the record, by a preponderance of the evidence and the weight of the argument. See *In Re Baisecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984).

The burden of establishing a *prima facie* case of obviousness thus rests upon the Examiner and can only be satisfied by showing an objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led such individual to combine the relevant teachings of the cited references. It is error to reconstruct the appellant's claimed invention from the prior art by using the appellant's claim as a "blueprint". For the reasons discussed, the prior art references cited by the Examiner do not suggest the invention, as a whole, defined by claim 1 or claim 13.

Considering Schubert and Hida in combination does not anticipate Applicant's invention and therefore claims 1 and 13 are allowable and claims 2-4 and 14 are allowable as further limitations on allowable independent claims.

B. Claim 5 stands rejected under 35 USC 103(a) as being unpatentable over Schubert in view of Hida (US 5,192,720) and further in view of Toibana (US 4,507,224).

The preceding arguments to Schubert and Hida are incorporated here. Toibana does not solve the deficiencies discussed above, for example, Toibana does not teach "coatings". The use of yttria to stabilize the phase transformation of zirconia is well known to those skilled in the art. Addition of 3 mole percent yttria is within a commonly accepted range and limits the yttria addition to this concentration. Claim 5 is allowable as a further limitation on an allowable claim 1.

VIII. CLAIMS APPENDIX

1. A degradation resistant composition of matter for use in living tissue, comprising:
 - an yttria-stabilized tetragonal zirconia polycrystal substrate;
 - a coating of alumina deposited on the substrate, said coating being deposited by ion beam assisted deposition in the presence of the substrate; and
 - wherein
 - said coating has a total porosity of less than about 1.0 percent.
2. The material of claim 1, wherein said coating has an average grain size less than about 0.5 microns.
3. The material of claim 1, wherein said coating comprises alpha-alumina, amorphous alumina, or a blend thereof.
4. The material of claim 1, wherein said coating has a thickness that is greater than about 1.6 micron and less than about 10 microns.
5. The material of claim 1, wherein said yttria-stabilized tetragonal zirconia polycrystal substrate comprises about 3 mole percent yttria.
- 6-12. (cancelled)
13. A degradation resistant composition of matter for use in living tissue, comprising:
 - an yttria-stabilized tetragonal zirconia polycrystal substrate;
 - a moisture resistant coating of alumina deposited on the substrate; wherein
 - said coating has a total porosity of less than about 1.0 percent.
14. The subject matter of claim 13, in which the coating is formed by ion beam assisted deposition.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None

XI. SPECIFICATION APPENDIX

None

A. Specification with line numbers added and incorporating all Amendments.

B. Figures incorporating all Amendments.

Respectfully submitted,

8/8/06

Date



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